

# THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



**GLOBALISATION**



**procurement**

## Key challenges in supplies management, BE's perspective

***Keeping up with Reality and Quality: A challenge for  
European Blood Establishments***

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## Facts and challenges – Procurement [Risk]

- In the EU, rules and regulations apply to all, **one size fits all**
- The size of the **local 'market'**, local may be national, regional or even just a blood establishment **[URS same for all does not fit a BE]** (a),
- Changing **scenarios [All lots non compliant-> disruption of supplies]**, which may require quick responses (b),
- Geographic issues, *e.g. natural events (storms, volcanoes, small islands)* **[Disruption of supplies]**,
- Financial constraints (c) **[material/device of lower quality]**
- Public Procurement (considered as Bureaucracy) should be a supporting tool:
  - Achieve right balance between technical and financial requirements,
  - Failure in tendering/non-compliant tender (d)



- (a) B-QM audit: in ~ 1/3 of BEs audited: procurement decentralised
- (b) B-QM audit/B-PTS studies: IH gel cards not suitable – small country with no possible alternative. ABO/Rh grouping reliability? Patients.
- (c) URS downgraded by MoH ▶ 'Non URS'/lower standard
- (d) B-QM audit: delayed implementation for NAT testing ▶ safety issue

## Facts and challenges – Procurement [Risk]

- Supplier (Parent company) **issues [Disruption of supplies]** (a)
- Local supplier **issues [Disruption of supplies]**
- Storage ability (BE, local supplier) **[associated risks]**
- Maintenance/Repairs (**timely!**) **[Disruption of business]**
- **Support ability** (how fast (including time for delivery), effective, availability of parts) **[Disruption of business]**, Esp. if 'insular'



- (a) B-PTS finding: Syphilis kit disruption in 2017

## Facts and challenges – Globalisation of market *[Risk]*

- **Reliance** on supplies produced in third countries, *mostly from Asia* **[Disruption of supplies]** (a)
- **Competitiveness** within Europe and between European/non European producers:
  - Manufacturer switch from tailor-made devices to standardised low priced devices produced at lower cost **[lower standard]** or,
  - leave the market **[Disruption]** or, (b)
  - Tailor-made devices (e.g. IT system) → limited competition → Monopoly → **[Reliance on one supplier]**
- **Few suppliers** for critical material (e.g. Blood Bags) **[Disruption]**,
- **High costs** due to economy of scale (e.g. NAT testing) (c)
- **Audit** of critical suppliers by BEs **[Costly]**



- (a) B-QM WG members: 90% BEs rely on supplies produced in third countries
- (b) B-QM audit: Disruption of a TTI testing kit in a country (EU) as no financial benefit
  - ▶ BE stopped processing as impossibility to release blood components ▶ patients at risk
- (c) B-QM audits: non affordable for several EU countries while NAT testing is key to ensure safety

## IMPACT ON BEs

- Extra-efforts to have back up or extra capacity,
- Expensive,
- Sustainability,
- Business continuity at risk,
- Donors and patients at risk



## Mitigation measures

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- **Procurement** (from URS/specification, tender and awarding): organised, timely, fit for purpose (included within Quality System) (**assess and mitigate risks**)
- **Contract Management** : Robust, timely, clear, contingency plan
- **Reputable** suppliers/local agents (**assess risks and mitigate risks**)
- **Very good relationship** with other Governmental agencies (National, regional or local) which may have an influence, e.g. Contracting Authority, Finance. (We do not function in a vacuum !)
- **Very good working relationship** with end users (Hospitals) and Competent Authority

## On a 'Bigger Scale'

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- Influencing decisions which impact supply management at **European Commission** level:
  - *Blood Directives, Public Procurement Legislation, Medical Devices,*
  - *GDPR, EU GMP*

***Either nationally or through other bodies EBA, CoE***

## But also..

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- **Working together**.....coordinate together
  - Sharing of knowledge, expertise, experience
  - Joint activities e.g. joint procurement, joint suppliers audits?
  - Back up support, e.g. testing.
  
- **Exemption** to procurement?
- **Recognition** of joint activities by EC and regulators?

## Some secrets of Success..

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- Have thorough understanding of your needs, future needs,
- Have strategic procurement,
- Plan very early – if possible months (if not years in major projects) in advance,
- Draft a very detailed tender document ,
- Set up an efficient Evaluation Committee dedicated to quickly arrive at recommendations,
- Contract Management during execution of works / services / supplies has to be continuous ,
- Contingency planning for delays,
- Acquire a good working relationship with contractors / suppliers / service providers / regulatory authorities.